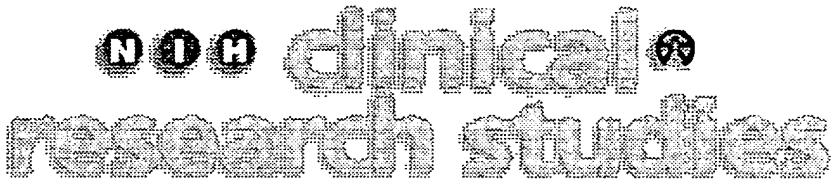

Protocol Number: 93-C-0066

Active Accrual, Protocols Recruiting New Patients

Title: Treatment of Tac-Expressing Adult T-Cell Leukemia with Yttrium-90 Labeled Humanized Anti-Tac Monoclonal Antibody

Number: 93-C-0066

Summary: Radioimmunoconjugate Therapy. Yttrium-90-Labeled Humanized Monoclonal Antibody anti-Tac, 90Y-MOAB anti-Tac, NSC-631937.

Sponsoring Institute:
National Cancer Institute (NCI)

Recruitment Detail
Type: Active Accrual Of New Subjects
Gender: Male & Female

Referral Letter Required: No

Population Exclusion(s): None

Eligibility Criteria:
DISEASE CHARACTERISTICS:

Histologically confirmed adult T-cell leukemia/lymphoma (ATL) All stages of Tac-expressing ATL eligible except smoldering ATL (less than 3% abnormal lymphocytes in the peripheral blood and no lymph node involvement).

At least 10% of peripheral blood, lymph node, or dermal malignant cells reactive with anti-Tac (as determined by immunofluorescent staining) OR soluble IL-2 receptor levels greater than 1,000 U.

Measurable disease required, i.e., greater than 10% abnormal (strongly Tac-expressing) cells in the peripheral blood.

No symptomatic CNS disease due to ATL.

Malignant cells in the CSF may be allowed.

Tropical spastic paraparesis allowed.

PRIOR/CONCURRENT THERAPY:

Biologic Therapy: Not specified.

Chemotherapy: Prior chemotherapy allowed; failure on an ongoing course of aggressive chemotherapy (i.e., manifesting progressive disease) excludes; at least 4 weeks since cytotoxic chemotherapy.

Endocrine Therapy: No delay required for patients receiving corticosteroids.

Radiotherapy: Prior radiotherapy allowed.

Surgery: Not specified.

PATIENT CHARACTERISTICS:

Age: 18 and over.

Performance status: Not specified.

Life expectancy: Greater than 1 month.

HEMATOPOIETIC:

AGC at least 1,000, Platelets at least 75,000.

HEPATIC:

Not specified.

RENAL:

Not specified.

OTHER:

No pregnant women.

Special Instructions:

Many protocols are potentially hazardous, are intended only for use by clinical oncologists in carefully structured settings, and may not prove to be more effective than standard treatment. A responsible investigator associated with this protocol should be consulted before using this protocol. Dose and schedule modifications are required for patients who develop gastrointestinal, hematologic, neurologic, and biochemical (renal, hepatic, etc.) and/or other abnormalities after the administration of therapy.

Additionally, Federal regulations for the protection of human subjects require approval of clinical trials by your local Institutional Review Board.

Disease Category:
Neoplasms

Keywords:
IL-2 Receptor
G-CSF (Granulocyte Colony-Stimulating Factor)
HTLV-I
Indium-111
HAMA (Human Antibodies to Monoclonal Antibody)

Recruitment Keywords:
None

Investigational Drug(s):
Yttrium-90 Humanized Anti-Tac

Investigational Device(s): None

Contacts:
Patient Recruitment and Public Liaison Office, CC.
Building 61
10 Cloister Court
Bethesda, Maryland 20892-4754
Long Distance Calls: 1-800-411-1222
Fax: (301) 480-9793
Electronic Mail:prpl@mail.cc.nih.gov

Citations:
Waldmann. 1986. The structure, function, and expression of interleukin-2 receptors on normal and malignant T cells, *Science, Vol. 232*, p. 727

Waldmann. 1988. Therapy of patients with human T-cell lymphotrophic virus I-induced adult T-cell leukemia with anti-Tac, a monoclonal antibody to the receptor for interleukin-2, *Blood, Vol. 72*, p. 1805

Kozak. 1989. The nature of the bifunctional chelating agent used for radioimmunotherapy with Yttrium-90 monoclonal antibodies is a critical factor in determining in vivo survival and organ toxicity, *Cancer Res, Vol. 49*, p. 2639

Active Accrual, Protocols Recruiting New Patients

If you have:

- Questions about participating in a study, please contact the Patient

Recruitment and Public Liaison Office, CC.

- Questions about specific studies, or the database in general, please contact the Protocol Coordination Service Center, CC.
- Technical questions regarding the Clinical Center web site, please contact the Information Systems Department, CC.

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Clinical Center Home | NIH Home

Warren Grant Magnuson Clinical Center (CC)
National Institutes of Health (NIH)
Bethesda, Maryland 20892. Last update: 06/02/99